AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/563,107

**REMARKS** 

Claims 1-16 and 19-20 are canceled. Claims 17-18 and 23 are amended. Support is

found, for example, in the original claims. No new matter is presented. Entry of the amendment

is respectfully requested.

I. Election/Restriction

In paragraph 1 of the Office Action, the Examiner acknowledges Applicants' election in

the Response filed March 6, 2008 of Group II, without traverse, which encompasses instant

claims 17 and 18. The Examiner also acknowledges new claims 21-24, which read on the

elected invention. Thus, the subject matter now under consideration is drawn to claims 17-18

and 21-24. Claims 1-16 and 19-20 have been canceled.

II. Priority

In paragraph 3 of the Office Action, the Examiner indicates that the prior-filed

application fails to provide adequate support or enablement in the manner provided by the first

paragraph of 35 U.S.C. §112 for one or more claims of the present application. The Examiner

states, "all claims are not adequately supported or enabled by the prior-filed applications for a

method of treatment".

The Examiner further states that Applicants are not entitled to the priority date of these

applications for all claims in the instant claim set because the prior filed foreign applications (JP

2003-189837 and JP 2003-420912) do not support Applicants' instantly claimed invention since

the prior filed applications are in the Japanese language and are not understood by the Examiner.

The Examiner concludes that all claims are given a priority date of June 30, 2004.

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In paragraph 4 of the Office Action, the Examiner indicates that the present application appears to claim subject matter disclosed in prior International Application PCT/JP04/09604, filed June 30, 2004, which claims priority to Foreign Patent Application JP 2003-189837, filed July 1, 2003 and JP 2003-420912, filed December 18, 2003. The Examiner further states that a reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a).

Applicants provide the following in response.

Regarding paragraph 3, Applicants are not required to submit certified English translations of the priority documents, unless Applicants intend to rely on the priority documents to overcome a reference. However, the Examiner is correct in that the effective U.S. filing date of the present application is June 30, 2004, which is the filing date of the international application, to the extent that a certified English translation of the Japanese application priority documents has not been submitted.

Applicants submit a certified English translation of Japanese application No. JP 2003-189837 filed in Japan on July 1, 2003 herewith to antedate the Igarishi et al reference as discussed below. Therefore, Applicants claim to foreign priority is perfected.

Regarding paragraph 4, the present application is a National Stage application under 35 U.S.C. § 371 and Applicants are not required to amend the first sentence of the application to reference the international application. The rules quoted by the Examiner relate to earlier applications, but the international application is not an earlier application because the national

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stage application and the international application are the same application and have the same filing date. Specifically, MPEP §1893.03(c)(III) states:

a national stage application submitted under 35 U.S.C. §371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the \*\*>international filing date of the< international application. See also MPEP § 1893.03(b). Stated differently, since the international application is not an earlier application (it has the same filing date as the national stage), a benefit claim under 35 U.S.C. §120 in the national stage to the international application is inappropriate and may result in the submission being treated as an application filed under 35 U.S.C. §111(a). See MPEP § 1893.03(a). Accordingly, it is not necessary for the applicant to amend the first sentence(s) of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage (emphasis added).

It is not clear whether the Examiner is requesting Applicants to amend the specification to also include a reference to the foreign priority applications. Although it is a common practice to include a reference to the foreign priority applications, there is no formal requirement for the specification to refer to the foreign priority applications. The requirements to obtain the right of foreign priority are (1) a claim for priority; and (2) the certified copy of the foreign application. The claim for foreign priority must identify the foreign application for which priority is claimed and may appear in the oath or declaration, an application data sheet, or the application transmittal letter with the recitation of the foreign application. These requirements have been met.

In view of the above, Applicants claim to foreign priority is proper and no amendments to the specification are necessary as stated above. However, the specification is amended as requested to appears the Examiner.

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### III. Information Disclosure Statement (IDS)

In paragraph 5, the Action indicates that the IDS and references submitted April 25, 2006 have been reviewed to the extent that each is a proper citation of a U.S. patent.

In paragraph 6, the Action indicates that the IDS filed February 17, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The Examiner states that the IDS has been placed in the application file, but the information referred to therein has not been considered. Specifically, the Examiner states that the foreign patent documents JP 2001-163862, JP 2001-507338, JP 2002-541095, JP 2004-2318 and JP 2004-504351 have not been provided.

In paragraph 7, the Action indicates that the listing of references in the Search Report is not considered to be a proper citation in compliance with 37 C.F.R. § 1.98.

Applicants note that the Examiner's reference to an IDS filed on February 17, 2006 appears to be a clerical error as no IDS was filed for the present application on February 17, 2006. However, it appears that the Examiner may be referring to the IDS filed April 25, 2006, since the JP references which the Examiner states were not provided are listed on the PTO/SB/08 Form submitted with the IDS filed April 25, 2006.

Regarding the IDS filed April 25, 2006, it is noted that the Examiner has crossed off the listed JP references, indicating that these references were not considered because, according to the Examiner, a copy of these references were not provided. However, each of the listed JP references, i.e., JP 2001-163862, JP 2001-507338, JP 2002-541095, JP 2004-2318 and JP 2004-504351 are present in the Image File Wrapper (IFW) for the present application on the U.S.

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PTO's website. A copy of the "Display References" tab of the IFW of the present application

and the first page of each of the listed JP references said to have not been provided is attached

for the Examiner's convenience. Therefore, the references were in fact provided and therefore

should be considered by the Examiner. Applicants also submit a copy of the PTO/SB/08 Form

filed with the IDS on April 25, 2006 and request the Examiner to initial or sign the form to

indicate that all of the references cited therein have been considered.

In response to the Examiner's comments regarding "the listing of references in the Search

Report", Applicants note that the International Search Report is submitted as an indication of the

degree of relevance of the listed references as found by the International Bureau in compliance

with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language

documents as indicated at page 2 of the IDS filed April 25, 2006. This is an accepted practice as

indicated by MPEP §609.04(a)(III), which states, "where the information listed is not in the

English language, but was cited in a search report or other action by a foreign patent office in a

counterpart foreign application, the requirement for a concise explanation of relevance can be

satisfied by submitting an English-language version of the search report or action which

indicates the degree of relevance found by the foreign office."

In addition to the citation in the International Search Report, a copy of JP 2001-163862

and an English translation thereof were submitted. Also, other references in the Japanese

language without English abstracts were submitted together with the corresponding U.S. Patents

or Canadian patent in the English language as follows:

JP 2001-507338 corresponds to US 2001/03745A1

JP 2002-541095 corresponds to CA2367051 A1

JP 2004-2318 corresponds to US 2005/96322 A1

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JP 2004-504351 corresponds to US 2003/216358 A1.

Thus, the Examiner should have considered the references in view of the citation in the International Search Report and in view of English language references submitted with the Japanese language references.

Accordingly, reconsideration of the IDS filed April 25, 2006 is respectfully requested.

### IV. Response to the Objection to the Title

In paragraph 8 of the Office Action, the title of the invention is objected to as not being descriptive. The following title is suggested by the Examiner: METHOD OF TREATING METABOLIC BONE DISEASE WITH A TRIAZOLO PYRIDAZINE AND BISPHOSPHONATE COMPOUND.

The title is amended herein as suggested by the Examiner, thereby obviating the objection.

Accordingly, Applicants respectfully request withdrawal of the objection.

# V. Response to Claim Rejection under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph

In paragraph 9 of the Office Action, claim 23 is rejected as being indefinite. The Examiner states that there is insufficient antecedent basis for the recitation, "the bisphosphonate".

Claim 23 is amended to depend directly from claim 17, thereby obviating the rejection.

Accordingly, Applicants request withdrawal of the rejection.

In paragraph 10 of the Office Action, the Examiner asserts that the recitation "and/or" in claim 17 and 18 at line 2 is confusing as to what method is being claimed.

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Applicants note that the term "and/or" is commonly used and is readily understood to refer to alternatives and also to a combination. That is, the phrase "and/or" indicates that one can either choose between two alternatives or choose both of them. For example, the recitation A and/or B is readily understood to refer to A or B and also to the combination of A and B. Thus, in the present case, the phrase "reduction of the bone mass and/or bone strength" refers to reduction of the bone mass or reduction of bone strength, and also to reduction of the bone mass and reduction of bone strength. As the meaning of this phrase is readily understood, one of ordinary skill in the art can easily ascertain the meaning and scope of the claim language.

Notwithstanding the above, claims 17 and 18 are amended herein, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

# VI. Response to Claim Rejections under 35 U.S.C. § 112, 1st Paragraph

In paragraph 11 of the Office Action, claims 17-18 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner asserts that the recited "method for prevention" is not enabled essentially because the prior art nor the instant application is enabling for prevention of metabolic bone diseases with the elected composition.

Applicants respectfully traverse the rejection based on the following.

Osteoporosis is recognized as a disease in which bone mass and/or bone quality are reduced and thus bone strength is reduced to increase the risk of bone fracture. It has been reported that 10,000,000 patients and the spare group of more than 18,000,000 people having

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reduced bone mass (left column of page 785 of Osteoporosis Prevention, Diagnosis, and Therapy JAMA. 2001; 285(6): 785-795 (a copy of this reference is attached as Attachment 1)).

This reference states, "WHO operationally defines osteoporosis as bone density 2.5 SDs below the mean for young white adult women. It is not clear how to apply this diagnostic criterion to men and children, or across ethnic groups" (in the middle column of page 786). With respect to osteoporosis, it is the current situation to draw a line between patients which require treatment and the spare group which require prevention based on the extent of the same cause of the disease. Accordingly, it is understood that an agent which can treat the cause of osteoporosis is useful in both of treatment and prevention of the disease. On the other hand, there is a case which has a possibility of a different effect of the agent (e.g., before infection and after infection in the case of infection disease). This situation with osteoporosis should not be judged in the same way.

Accordingly, in this technical field, it is apparent that an agent having an effect to improve bone mass and/or bone strength is useful as an agent for treatment for patients having a bone mass which is lower than a certain level and is useful as an agent for prevention for the patients having a bone mass which is higher than a certain level. Thus, it is understood by those of ordinary skill in the art that the agent can be used for both purposes.

In fact, in the clinical reports about osteoporosis, there are reports in which both of the prevention and treatment are objects, which is clear from the use of the phrase "prevention and treatment of osteoporosis".

(1) Bisphosphonates: from the laboratory to the clinic and back again (Bone, Volume 25, Issue 1, July 1999, Pages 97-106). (Copy is attached as Attachment 2).

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(2) Biochemical markers for prediction of 4-year response in bone mass during bisphosphonate treatment for prevention of postmenopausal osteoporosis (Bone, Volume 33, Issue 1, July 2003, Pages 150-158). (Copy is not attached).

- (3) The effect on bone mass and bone markers of different doses of ibandronate: A new bisphosphonate for prevention and treatment of postmenopausal osteoporosis: A 1-year, randomized, double-blind, placebo-controlled dose-finding study (Bone, Volume 19, Issue 5, November 1996, Pages 527-533). (Copy is not attached).
- (4) Estrogen-dependent increase in bone turnover and bone loss in postmenopausal women with breast cancer treated with anastrozole. Prevention with bisphosphonates (Bone, Volume 41, Issue 3, September 2007, Pages 346-352). (Copy is not attached).

In addition, there are many U.S. patents wherein claims to "prevention and treatment of osteoporosis" have been allowed (e.g., U.S. RE390,50E1, U.S. 6,953,791B2, U.S. 5,951,850B2, U.S. 6,924,280B2, and U.S. 7,138,392B2).

Moreover, it has been proven in the present application that use of a combination of a non-living body-derived non-peptide osteoblast differentiation promoting compound and a bisphosphonate has an effect of increasing bone mass or increasing bone strength in the osteoporosis model animal. Accordingly, in addition to the method of treatment of a metabolic bone disease which accompanies reduction of the bone mass which is achieved by the above effect, a method of prevention for the patients of a spare group of such a disease should be allowed.

Accordingly, Applicants respectfully request withdrawal of the rejection.

### VII. Response to Claim Rejection under 35 U.S.C. § 103

In paragraph 12 of the Office Action, claims 17-18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igarashi et al. (US Patent 7,173,033) in view of Burk (US Patent 6,174,857).

Applicants claim priority to Japanese priority application, JP 2003-189837, filed in Japan on July 1, 2003, which precedes the earliest effective prior art date of Igarashi et al, and respectfully submit a sworn English translation of the priority document to remove Igarashi et al as a reference.

The critical reference date of Igarashi et al is determined as follows.

The currently recognized effective filing date of the present application is the filing date of the international application filed on June 30, 2004.

The Igarashi application (the '859 application) that resulted in the '033 patent is a continuation of App. No. 10/505,393, filed as PCT/JP03/02248 on February 27, 2003. However, International Application No. PCT/JP03/02248, (published as WO2003/074525) (WO '525) was not published in English. Therefore, the international filing date can not be treated as the U.S. filing date for prior art purposes. See MPEP §706.02(f)(1)(I) and §2136.03(II).

The Igarashi reference may only be applied under 35 U.S.C. §102(a) or (b) as of its publication date, or 35 U.S.C. §102(e) as of any later U.S. filing date of an application that properly claimed the benefit of the international application. Id.

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Taking this into consideration, the '033 patent publication does not qualify as prior art since the publication date of February 6, 2007 is after the effective filing date of the present application of June 30, 2004.

Further, the '033 patent would only be entitled to §102(e) date as of its U.S. filing date, i.e., the filing date of the '859 application which is July 28, 2005. This date is after the effective filing date of the present application of June 30, 2004 and therefore, Igarashi et al does not qualify as §102(e) art.

The international application publication, WO 2003/074525 (WO '525), was published on September 12, 2003, which is before the effective filing date of the present application of June 30, 2004. Thus, the WO '525 publication qualifies as a reference under §102(a). However, Applicants have antedated the §102(a) date of the WO '525 publication by filing a sworn English translation of Applicants' Japanese priority application, JP 2003-189837, filed in Japan on July 1, 2003, which precedes the publication date of WO '525 of September 12, 2003 to remove the WO '525 publication as a reference against the present application.

The claimed invention is supported by the priority application as follows:

The present claims	Support in JP 2003-189837		
17	page 16, lines 11-23; page 36, line 13 to page 37, line 2		
18	page 15, line 16 to page 16, line 23		
21	page 18, line 18 to page 20, line 25		
22	page 32, lines 9-25		
23	page 34, line 11 to page 35, line 2		
24	page 52, line 25 to p. 53, line 15		

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Thus, Igarashi et al is not legally effective prior art to the present application and Burk fails to teach or suggest all elements of the present claims. Thus, the present invention is not

rendered obvious.

Accordingly, Applicants respectfully request withdrawal of the rejection.

VIII. Response to Obviousness-Type Double Patenting Rejection

In paragraph 13 of the Office Action, claims 17-18 and 21-24 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 5 and 7

of U.S. Patent No. 7,173,033 (Igarashi et al.), in view of Burk.

Applicants respectfully traverse the rejection.

While Igarashi et al and Burk are generally related to similar therapeutic methods, the

active agents are totally different. Igarashi et al claims a nitrogen-containing heterocyclic

compound respresented by formula (I) as described in the reference, whereas Burk teaches

Insulin-like Growth Factor (IGF-1), which is a 70 amino acid peptide that retains structural and

biological similarities to insulin. See column 1, lines 49-52. There is no structural similarity

between these two agents and in view of the structural differences of these agents one of ordinary

skill in the art would not have been motivated to modify and/or combine the references as

suggested by the Examiner.

Additionally, the present invention is directed to a small chemical molecule osteoblast

differentiating promoting compound, whereas the IGF-I of Burk is a naturally occurring protein

preferably from the same species being treated therewith. See, e.g., column 2, lines 45-47.

Thus, one of ordinary skill in the art would not have had a reasonable expectation of success in

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modifying or combining the references of achieving a method involving use of a non-living

body-derived non-peptide osteoblast differentiating promoting compound.

Accordingly, Applicants respectfully request withdrawal of the obviousness-type double

patenting rejection.

Conclusion IX.

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

Registration No. 40,641

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WASHINGTON DC SUGHRUE/265550

65565

CUSTOMER NUMBER

Date: September 16, 2008

		07-17-
10/563,107	Bone mass increasing inducer	2008::13:59:58

# **U.S. Patent Documents**

How to download references 3 Form(s) Found for Application Number 10/563,107

Date	Form Type
04-25-2006	IDS
02-03-2008	PTO-892
05-30-2008	PTO-892

Reference Form	Reference Forms				
Mail Room Date	Document Code	Document Description	Page Count		
06-16-2008	892	List of references cited by examiner	1		
06-16-2008	1449	List of References cited by applicant and considered by examiner	2		
02-11-2008	892	List of references cited by examiner	1		
OZ 11 ZOOO					

Mail Room I	Date Docum	ent Code	<b>Document Description</b>	Page Count
06-16-2008	NPL	NPL Documents		2
04-25-2006	FOR	Foreign Reference		46 (
04-25-2006	FOR	Foreign Reference		58
04-25-2006	FOR	Foreign Reference		38
04-25-2006	FOR	Foreign Reference		43
04-25-2006	FOR	Foreign Reference		15
04-25-2006	FOR	Foreign Reference		39
04-25-2006	FOR	Foreign Reference		27
04-25-2006	FOR	Foreign Reference		50
04-25-2006	FOR	Foreign Reference		10
04-25-2006	FOR	Foreign Reference		13
04-25-2006	FOR	Foreign Reference		10
04-25-2006	FOR	Foreign Reference		5
04-25-2006	NPL	NPL Documents		7
04-25-2006	NPL.	NPL Documents		8
04-25-2006	NPL	NPL Documents		1
04-25-2006	NPL	NPL Documents		9
04-25-2006	NPL	NPL Documents		2
04-25-2006	NPL	NPL Documents		3
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# (12) 公開特許公報(A)

(11)特許出顧公開番号 特開2001-163862 (P2001-163862A)

(43)公開日 平成13年6月19日(2001.6.19)

(51) Int.Cl. <sup>7</sup>	識別記号	FI	テーマコード(参考)
C 0 7 D 237/04		C 0 7 D 237/04	4 C 0 6 3
A61K 31/50		A 6 1 K 31/50	. 4C086
31/501		31/501	
A61P 43/00	111	A61P 43/00 11	1 1
C 0 7 D 401/12		C 0 7 D 401/12	
C 0 7 D 401/12		審査請求 未請求 請求項の要	t5 OL (全 41 頁)
(21)出願番号	特顧2000-289991(P2000-289991)	(71)出額人 000001856	
(00) 山麓日	平成12年9月25日(2000.9.25)	三共株式会社東京都中央区日本植	峰本町3丁目5番1号
(22)出顧日		(72)発明者 柴田 智之	
(31)優先権主張番号	特願平11-271881	東京都品川区広町	丁目2番58号 三共株
(32)優先日	平成11年9月27日(1999.9.27)	式会社内	
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(00) 西沙山市出土。北西	Hotel ( a m )	東京都品川区広町	1丁目2番58号 三共株
		式会社内	
		(74) 代理人 100081400	
		弁理士 大野 彰元	失 (外2名)
			最終頁に続く

### (54) 【発明の名称】 テトラヒドロピリダジン誘導体

#### (57) 【要約】

【課題】 優れたマトリックスメタブロティナーゼ阻害 活性を有する新規なテトラヒドロピリダジン誘導体を提 供する。

【解決手段】 下記一般式(I) 【化1】

(式中、 $R^1$ は、同一または異なる $1\sim3$ 個の置換基で置換されていても良い $C1\sim C12$  アルキル基、アリール基、ビアリール基、ヘテロアリール基、アリールアルキル基、ピアリールアルキル基、またはヘテロアリールアルキル基を示し、 $R^2$ 、 $R^3$ 、 $R^4$ 、 $R^5$ 及び $R^6$ は各々独立に水素原子、 $C1\sim C4$  アルキル基またはアリール基を示し、XはOH基またはNHOH基を示す。)で表わされる化合物またはその薬理上許容される塩並びにそれ

らを含有する医薬組成物。

#### (19)日本国特許庁(JP)

# (12) 公表特許公報(A)

(11)特許出顧公表番号 特表2001-507338 (P2001-507338A)

(43)公表日 平成13年6月5日(2001.6.5)

(51) Int.Cl.7	識別記号	F I デーマコート* (参考)
A61K 31/568		A 6 1 K 31/568
31/663		31/663
A61P 3/14		A61P 3/14
19/08		19/08
19/10		19/10
		審査請求 未請求 予備審査請求 有 (全 15 頁
(21)出願番号	<b>特顧平10-524753</b>	(71)出願人 メルク エンド カンパニー インコー
(86) (22)出願日	平成9年11月21日(1997.11.21)	レーテッド
(85)翻訳文提出日	平成11年5月12日(1999.5.12)	アメリカ合衆国、ニュージャーシィ
(86)国際出願番号	PCT/US97/21306	07065, ローウエイ, イースト リンカー
(87)国際公開番号	WO98/23274	ン アヴェニュー 126
(87)国際公開日	平成10年6月4日(1998.6.4)	(72)発明者 シユミツト,アズリエル
(31)優先権主張番号	60/031, 734	アメリカ合衆国、ニユー・ジヤージー・
(32)優先日	平成8年11月25日(1996.11.25)	07065、ローウエイ、イースト・リンカー
(33)優先權主張国	米国 (US)	ン・アベニユー・126
(31)優先權主張番号	60/032, 341	(74)代理人 弁理士 川口 錢雄 (外2名)
(32)優先日	平成8年12月4日(1996.12.4)	
(33)優先権主張国	米国 (US)	
		最終頁に

(54) 【発明の名称】 疾患を治療するために同時投与されるアンドロゲン物質とビスホスホン酸物質

### (57)【要約】

ピスホスホン酸あるいはその製薬学的に許容しうる塩に よる骨吸収疾患の予防および/あるいは治療において経 験される自然骨形成の抑制が、アンドロゲン物質の併用 投与によって克服される。

#### (19) 日本国特許庁 (JP)

# (12) 公表特許公報(A)

(11)特許出願公表番号 特表2002-541095 (P2002-541095A)

(43)公表日 平成14年12月3日(2002.12.3)

(51) Int.Cl. <sup>7</sup>	徽別記号	FΙ	テーマコート* (参考)
A61K 31/50		A61K 31/50	4 C 0 8 6
A61P 1/04		A61P 1/04	
3/10		3/10	
9/10	101	9/10	101
17/00		17/00	
·	審查請求	未請求 予備審査請求 有	(全39頁) 最終頁に続く
(21)出顧番号	特顧2000-609048(P2000-609048)	(71)出願人 メルク パテ	ント ゲゼルシャフト ミッ
(86) (22)出顧日	平成12年3月15日(2000.3.15)	トペシュレ	ンクテル ハフトング
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(33)優先権主張国	ドイツ (DE)	(74)代理人 弁理士 金田	暢之 (外2名)

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#### (54) 【発明の名称】 アリールアルカノイルピリダジンの使用

#### (57) 【要約】

本発明は、骨粗鬆症、腫瘍、アテローム性動脈硬化症、 慢性関節リウマチ、多発性硬化症、真性糖尿病、潰瘍性 大腸炎およびAIDS治療のための薬剤を製造するため の、R<sup>1</sup>、R<sup>2</sup>、QおよびBが酵求項1において与えられ る意味を有する式(I)の化合物群、および/または生 理学的に適合するそれらの塩の利用に関する。

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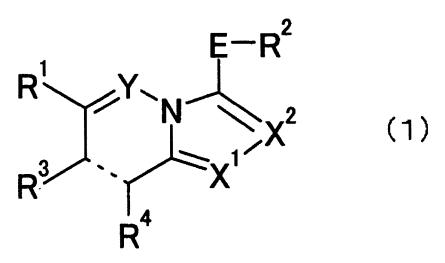
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			最終頁に続く

#### (54) 【発明の名称】含窒素複素環化合物

### (57) 【要約】 (修正有)

【課題】骨粗鬆症等の代謝性骨疾患に必要な骨芽細胞の促進作用を有する治療薬を提供する。 【解決手段】下記1式で示される含窒素複素環化合物又はその製薬学的に許容される塩。



 $(X^1$ 及び $X^2$ はN又は $CR^5$ 、少なくとも一方はNを、YはN又は $X^1$ 及び $X^2$ が共にNのときYは $CR^6$ を、 $R^1$ は-NRaRb、アリール、シクロアルキル等を、又Ra及びRbはH、CO-低級アルキル等を、Eは単結合、C

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#### (54) 【発明の名称】骨量増加の増強方法

#### (57) 【要約】

本発明は、増強を必要とするヒトに骨増強量のラロキシフェンまたはその医薬的に許容しうる塩もしくは溶媒 和物を投与することを含む、先行するビスホスホネート療法を通して得られた骨量増加を増強する方法に関す る。

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### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 2

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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